

III. REMARKS

Status of the Claims

Claims 1-7 and 10-53 remain in the case. Claims 31, 32, 37, 40, 46, and 49 have been amended to more clearly describe that which the Applicant considers to be his invention. No new matter is added by these amendments, nor is it believed that any subject matter has been surrendered.

Telephone Interview

Applicant appreciates the courteous and helpful telephone interview granted by Examiner Henley on October 18, 2004. During the interview, Examiner Henley provided guidance as to possible amendments to clarify which routes of administration could be considered non-topical.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-7, 10-39, 45, 48, 51, and 53 are rejected under 35 U.S.C. § 112, second paragraph as indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Claims 31, 32, 37, 40, 46, and 49 have been amended to clarify the term non-topical administration as used in the independent claims. Applicant believes that by amending these claims to remove terms such as "cream," "gel," "ointment," and routes of administration such as "mucosal," "ocular," and "aural" that any inconsistency between the independent claims and dependent claims has been removed. Applicant believes that one of skill in the art reading the claims would understand, for example, that the liquid of claim 31 must be formulated for non-topical administration since claim 31 depends from independent claims directed to compositions "not formulated for topical administration" since any dependent claim must, by definition, meet all the limitations of the independent claim from which it depends. Applicant respectfully requests that the 35 U.S.C. § 112 rejections be withdrawn.

Claim Rejections Under 35 U.S.C. § 103

Claims 1, 2, 16, 29, 31-34, 37-44, and 45-53 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bergamini et al. Independent claims 33, 45, 48, and 51 were previously amended to be directed to non-topical administration as suggested by the Examiner. Claims 31, 32, 37, 40, 46, and 49 have now been amended to remove the recitations of dosage forms/routes of administration that would be considered exclusively topical. As stated above, the dependent claims must incorporate all limitations of the independent claim from which it depends. Thus, one of skill in the art would understand that the dosage forms which remain in those claims must be formulated for non-topical administration.

Further, the citations from REMINGTON'S cited by the Applicant previously distinguish between topical administration and others including oral, rectal (for example, via suppository), sublingual or buccal, parenteral, and inhalation. REMINGTON'S at 712. Specifically, while REMINGTON'S does mention that topical drugs are "also applied to the eye, nose and throat, ear, vagina, etc." as the Examiner points out, it distinguishes over the various other routes of administration. The preliminary comments at REMINGTON'S, p. 710 state:


[I]t might be expected that the particular site of application (or *route*) would make little difference to the successful absorption of the drug. In actual fact it makes a great deal of difference; many factors, other than structure and composition of the membrane, determine the ease with which a drug is absorbed.

As REMINGTON'S then goes on to distinguish between topical administration and other forms of administration, one of skill in the art would recognize that topical administration would require different formulations than oral, rectal, or parenteral administration, for example, to achieve optimal drug absorption and efficacy. Thus, Applicant respectfully requests that the 35 U.S.C. § 103 rejection be withdrawn.

Conclusion

Applicant submits that, based on the Amendments and Remarks herein, the claims are in condition for allowance and such favorable action is respectfully requested. If the Examiner has any questions or comments that might accelerate allowance of these claims, he is invited to contact the undersigned representative at (512) 542-8530.

Respectfully submitted,



Michael J. Smith
Reg. No. 51,381

Vinson & Elkins L.L.P.
2300 First City Tower
1001 Fannin Street
Houston, TX 77002-6760
(512) 542-8530

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